UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

BARRY MCCLAMROCK,

Plaintiff,

– against –

ELI LILLY & COMPANY,

Defendant.

MEMORANDUM, ORDER, AND JUDGMENT

04-MD-1596

04-CV-1613

JACK B. WEINSTEIN, Senior United States District Judge:

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I. Introduction

Defendant Eli Lilly & Company ("Lilly") moves for summary judgment against plaintiff Barry McClamrock. Plaintiff commenced this action against Lilly in the United States District Court for the District of Columbia on December 6, 2002. The case was transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

The present action is essentially a negligence claim, based on a failure to warn. It seeks money damages for injuries, alleging that: (1) Zyprexa, a drug produced by Lilly, caused plaintiff's diabetes and his various diabetes-related complications, including the amputation of part of his left leg and a toe on his right foot; (2) Lilly failed to warn of the dangers of Zyprexa; and (3) Zyprexa would not have been prescribed, and plaintiff's injuries would not have been suffered, if proper warnings had been given. Plaintiff's complaint also includes claims for strict liability, breach of warranty, and fraud.

For the reasons indicated below, defendant's motion for summary judgment is granted.

II. Facts

The present case is part of a massive and highly complex multidistrict litigation that has included claims by individual Zyprexa users, state attorneys general, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with Zyprexa. Like the present plaintiff, they principally allege that Zyprexa caused deleterious side effects, including excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending

physicians been aware of the risks, they would not have taken Zyprexa. The court has previously detailed the procedural history and factual background of this multidistrict litigation. *See, e.g., Mississippi v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 671 F. Supp. 2d 397 (E.D.N.Y. 2009); *Blume v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3596982 (E.D.N.Y. Oct. 20, 2009).

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine; it is one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. FDA Labeling and the "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses $\geq$ 2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient

> characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert 11 (Oct. 1, 1996) (original emphasis).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Part II.B.4, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmacological Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 119 (E.D.N.Y. 2008). There is disagreement about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003, at 1-2. The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Zyprexa Package Insert (Sept. 16, 2003). At the FDA's request, on March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. Consensus Statement of American Diabetes Association and Other Learned Groups

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .

***

Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

***

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

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[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.

Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

***

These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to

> differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

American Diabetes Association, et al., Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 27 Diabetes Care 596, 596-97 (Feb. 2004)

3. FDA March 2007 Letter

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. Findings on Medical Community's Knowledge of Zyprexa's Risks

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent

moments at which a patient, health care provider, institution, or the medical community at large arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of these motions, the March 1, 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 278 (E.D.N.Y. 2007). In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that the claim of one of the plaintiffs was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's

> duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.
>
> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew of the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.,* Appendices A-D of *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.),* Nos. 04-MD-1596, 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (E.D.N.Y. June 11, 2007) (including relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Barry McClamrock's Medical History and Treating Physicians' Decision to Prescribe Zyprexa

Barry McClamrock, who recently turned 59, *see* Pl.'s Fact Sheet 2 (Def. Ex. 1), has exhibited symptoms of mental illness since his late teens, *see* Def.'s Statement of Undisputed Material Facts ("Def.'s 56.1 Stmt") ¶ 11. His documented mental health history includes hallucinations, bipolar disorder, suicidal ideation, and schizoaffective disorder. Def.'s 56.1 Stmt ¶¶ 10-11, 23.

In January 1998, Mr. McClamrock was seen by Dr. Warren Williams, M.D., who diagnosed him as having schizoaffective disorder, bipolar type. *See id.* ¶ 18. Dr. Williams prescribed Zyprexa. *Id.* One week later, Dr. Williams discontinued plaintiff's Zyprexa prescription, but continued plaintiff's prescriptions for Prolixin and lithium. *See id.*

On December 8, 1998, Mr. McClamrock reported to Dr. Williams that he was doing badly. Dr. Williams contacted the Charter Pines Hospital in Charlotte, North Carolina, so that plaintiff could be admitted that day for treatment by the hospital's then-medical director, Dr. James Cockerill, M.D. Dr. Cockerill's psychiatric assessment indicated that, upon admission to the hospital, Mr. McClamrock was suicidal. *Id.* ¶¶ 22-23. He placed plaintiff on suicide precautions. *Id.* ¶ 24.

At the time of his admission to Charter Pines, Mr. McClamrock had prescriptions for, *inter alia*, Prolixin, Lithonate, and Prozac. According to Dr. Cockerill, these medications were not sufficiently effective. *See id.* ¶¶ 27-28. After discussing plaintiff's case with Dr. Williams, Dr. Cockerill decided to transition plaintiff from Prolixin to Zyprexa, in an attempt to target the negative symptoms of plaintiff's schizophrenia and to treat his depression. *Id.* ¶¶ 29, 31.

Mr. McClamrock began taking Zyprexa on December 11, 1998, and appeared to respond well to the medication. *Id.* ¶ 29, 32-36. Plaintiff was discharged from Charter Pines on

December 15, 1998. *Id.* ¶ 29. He was to continue on Zyprexa, meet with his psychiatrist, and meet with his primary care physician; he was also referred to the day program at Piedmont Mental Health Center. *Id.* ¶ 38.

Plaintiff continued to be prescribed Zyprexa by Dr. Williams throughout 1999; his last prescription for the medication was filled in November of that year. *Id.* ¶ 40.

Plaintiff's brother, who has plaintiff's power of attorney, knew of the fact that plaintiff was taking Zyprexa in 1999. Plaintiff, along with his family, concluded in 1999 that Zyprexa caused his diabetes and discontinued its use for plaintiff in that year. *See* October 14, 2011 Hearing Transcript.

III. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see, e.g., Mitchell v. Washingtonville Cent. Sch. Dist.*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255.

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see, e.g., Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a question of material

fact to defeat the motion. *See* Fed. R. Civ. P. 56(c). This evidence may not consist of "mere conclusory allegations, speculation or conjecture." *Cifarelli v. Vill. of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see Del. & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

A multidistrict litigation transferee court applies the choice of law and statute of limitations rules of the state in which the action was filed. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in the United States District Court for the District of Columbia, *see* Complaint 1 (Def. Ex. 2), that city's choice of law principles apply.

The District of Columbia's choice of law principles require that North Carolina substantive law apply to the instant litigation. In determining which jurisdiction's substantive law to apply, District of Columbia courts determine which jurisdiction has the most significant relationship with the litigation, and which jurisdiction's policy would be more advanced by applying its law. *See, e.g., USA Waste of Md. v. Love*, 954 A.2d 1027, 1030 (D.C. 2008). In determining which jurisdiction has the most significant relationship with the litigation, District of Columbia courts consider four factors: (1) the place where the injury occurred, (2) the place where the conduct causing the injury occurred, (3) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (4) the place where the relationship is centered. *See Dist. of Columbia v. Coleman*, 667 A.2d 811, 816 (D.C. 1995).

In this case, plaintiff is a resident of North Carolina, and all relevant conduct took place in that state. Mr. McClamrock was prescribed Zyprexa in North Carolina, all of his known

physicians practice in that state, and he was hospitalized there. Because North Carolina is the only state with a legitimate interest in the resolution of this litigation, the court will apply North Carolina law to adjudicate plaintiff's claims.

C. North Carolina Law—Learned Intermediary Doctrine

Plaintiff's complaint rests on the basic allegation that Lilly negligently failed to warn him about the risks of Zyprexa. North Carolina's products liability statute provides that no manufacturer of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant (1) "proves that the manufacturer . . . acted unreasonably in failing to provide such warning or instruction," (2) that "the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought," and (3) either (a) that at the time the product left the manufacturer's control, its lack of adequate warning created an unreasonably dangerous condition of which the manufacturer knew or should have known, or (b) that after the product left the manufacturer's control, the manufacturer became or should have become aware in the exercise of ordinary care that the product posed a substantial risk of harm to a reasonably foreseeable consumer, and failed to take reasonable steps to give an adequate warning of the danger. *See* N.C. Gen. Stat. Ann. § 99B-5(a) (West 2010).

North Carolina appears to have adopted the learned intermediary doctrine. *See, e.g.*, *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535-36 (E.D.N.C. 1987). The learned intermediary doctrine provides, essentially, that (1) manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing adequate warnings to prescribing physicians, and (2) that any failure to warn a patient cannot be considered a

proximate cause of a subsequent injury if the physician was fully aware of the dangers that would have been included in an alternative warning. *See Shepherd v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 10-CV-1757, 2011 WL 2516333 (E.D.N.Y. June 23, 2011).

The learned intermediary defense is an

> aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians . . . . [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.

Souther, 489 F. Supp. 2d at 244. There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well-established doctrine. *See, e.g., Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (concluding that summary judgment was proper where the "doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [the drug] . . . . Pursuant to Georgia's learned intermediary doctrine, this assertion severs any potential chain of causation."); *Motus v. Pfizer Inc., (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician") (citing *Plummer v. Lederle Labs.*, 819 F.2d 349, 358-59 (2d Cir. 1987)); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have

prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 F. App'x 350 (5th Cir. 2009) (per curiam); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at *3 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because plaintiff had failed to show (1) that defendant did not adequately warn the physician of a risk associated with the drug that was not otherwise known to the physician and (2) that the "failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 314 F. App'x 701 (5th Cir. 2009) (per curiam).

IV. Application of Law to Facts

"Under the learned intermediary doctrine, patients of an adequately warned prescribing physician cannot maintain a products liability action against a drug manufacturer because 'a manufacturer or seller of a prescription drug has no legal duty to warn a patient of the dangerous tendencies of its drug, as long as sufficient warnings are provided the prescribing physician.'" *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 269 (E.D.N.Y. 2007) (quoting *Dellinger v. Pfizer, Inc.*, No. 05:03CV95, 2006 WL 2057654, at *6 (W.D.N.C. July 19, 2006) (applying North Carolina law)). "A seller or manufacturer must act unreasonably to be held liable for failure to provide adequate warning under North Carolina law. . . . Where the evidence that the prescribing physician was adequately warned is not contradicted, the drug manufacturer has satisfied its duty to warn the learned intermediary and summary judgment may be granted." *Id.*

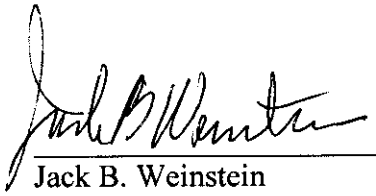
Dr. Cockerill, the psychiatrist who prescribed Zyprexa to plaintiff, testified that he was aware of the risks of the medication and that he thought the benefits of the medication outweighed the risks. *See* Def.'s 56.1 Stmt ¶¶ 46, 48-49. Nevertheless, he chose to prescribe Zyprexa in the exercise of his discretion as a learned intermediary. Plaintiff has not contradicted this evidence. Lilly satisfied its duty to warn under North Carolina law. *See Souther*, 489 F. Supp. 2d at 269.

Since plaintiff's psychiatrist was informed of the risks of Zyprexa at the time he made his prescribing decision, pursuant to the learned intermediary doctrine Lilly was not the proximate cause of plaintiff's injuries, and cannot be liable under a failure-to-warn theory.

V. Conclusion

Summary judgment against the plaintiff is granted. The clerk is ordered to close the case. No costs or disbursements are granted.

SO ORDERED.



Jack B. Weinstein
Senior United States District Judge

Date: October 14, 2011
Brooklyn, New York